



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2011-N-0003]

Oral Dosage Form New Animal Drugs; Deracoxib

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The supplemental NADA provides for veterinary prescription use of deracoxib tablets in dogs for the control of postoperative pain and inflammation associated with dental surgery and the addition of a 12-milligram (mg) size tablet.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to NADA 141-203 that provides for veterinary prescription use of DERAMAXX (deracoxib) Chewable Tablets in dogs for the control of postoperative pain and inflammation associated with dental surgery and the addition of a 12-mg size tablet. The supplemental NADA is approved as of November 23, 2011, and 21 CFR 520.538 is amended to reflect the approval.

A summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. In § 520.538, revise paragraphs (a), (d)(1), and (d)(2) to read as follows:

§ 520.538 Deracoxib.

(a) Specifications. Each tablet contains 12, 25, 50, 75, or 100 milligrams (mg) deracoxib.

\* \* \* \* \*

(d) \* \* \*

(1) Amount. Administer orally as needed, as a single daily dose based on body weight:

(i) 1 to 2 mg/kilogram (kg) (0.45 to 0.91 mg/pound (lb)), for use as in paragraph (d)(2)(i) of this section.

(ii) 1 to 2 mg/kg (0.45 to 0.91 mg/lb) for 3 days, for use as in paragraph (d)(2)(ii) of this section.

(iii) 3 to 4 mg/kg (1.4 to 1.8 mg/lb) for up to 7 days, for use as in paragraph (d)(2)(iii) of this section.

(2) Indications for use. (i) For the control of pain and inflammation associated with osteoarthritis.

(ii) For the control of postoperative pain and inflammation associated with dental surgery.

(iii) For the control of postoperative pain and inflammation associated with orthopedic surgery.

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Dated: January 23, 2012.

William T. Flynn,

Acting Director,

Center for Veterinary Medicine.

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